

**REMARKS/ARGUMENTS*****Status of Claims***

~~Claims 1, 14, and 53 have been amended.~~

Claims 35-52 were previously canceled.

Claim 34 is currently canceled.

Claims 4-10 have been withdrawn.

Thus, claims 1-3, 11-33, and 53 are currently pending in this application.

Applicants hereby request further examination and reconsideration of the presently claimed application.

***Claim Rejections – 35 U.S.C. § 112***

Claim 34 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have canceled claim 34 thus rendering this rejection moot.

***Claim Rejections – 35 U.S.C. § 102***

Claims 1-3, 11-22, 25-32, 34, and 53 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Jasprova, WO 02/03963 (hereinafter *Jasprova*). Claims 1-3, 11-22, 25-32, and 34 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Jasprova, WO 02/03963 (hereinafter *Jasprova*). Claim 34 has been canceled. Claims 2-3, 11-13, and 25-35 depend from independent claim 1, and claims 15-24 depend from independent claim 14. Thus, claims 2-3, 11-22 and 25-32 stand or fall on the application of *Jasprova* to independent claims 1 and 14. According to MPEP § 2131, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Applicants submit that *Jasprova* fails to teach “each and every” element of independent claims 1 and 14.

Specifically, Applicants submit that *Jasprova* fails to teach an oral formulation which includes an intragranular phase. Independent claims 1 and 14 have been amended to mirror original claims 1 and 14 respectively and recite:

1. An oral formulation **which includes an intragranular phase** comprising a bisphosphonic acid derivative and at least one carbohydrate alcohol, **together with an aqueous binder.**

14. An oral formulation **which includes an intragranular phase** comprising a bisphosphonic acid derivative and a carbohydrate alcohol which is mannitol, **together with an aqueous binder.**

*See supra* (Emphasis added). As shown above, each of independent claims 1 and 14 recites *an oral formulation which includes an intragranular phase*. To the contrary, *Jasprova* teaches:

As is documented below in the Examples, the combination of diluents according to the invention with exclusion of lactose makes it possible to obtain acceptable properties of the tablets in an economic compressing process, regardless of sensitive substances, which is **free of any granulation or pre-granulation of the components.**

*See Jasprova* at 9. Thus, *Jasprova* does not teach a granulation step; as such, *Jasprova* cannot teach an oral formulation which includes an intragranular phase. Applicants note that the Office Action dated May 8, 2009 (hereinafter *OA05082009*) indicated the aforementioned limitations were unpersuasive to distinguish the instantly claimed subject matter over that of *Jasporova*'s as the instant claims are product claims and not directed towards a method of making the claimed composition. *See OA05082009* at 4. Applicants agree that the instant claims are directed toward a product. However, the Applicants' instantly claimed subject matter is a composition having a particular structure (i.e., intragranular phase) that was imposed on the compositions as a result of the process by which it is prepared. Such compositions with similar structural limitations are necessarily absent from the disclosure of *Jasporova* which uses "direct compression" of the disclosed components and avoids granulation. The Examiner has asserted that *Jasporova* discloses the same physical constituents in the same "phase" of the composition. *See*

OA05082009 at 4. Applicants agree that physical constituents present in the *Jasprova* composition reside in the same “phase.” Applicants contend that the Examiner does not and cannot support the assertion that this “phase” is equivalent to the instantly claimed ***intragranular phase*** absent a granulation process. Such an assertion would be comparable to suggesting a cake is identical to a crepe which is identical to an egg tart based on the fact that they can each be prepared using the same set of ingredients and ignoring the structure imposed by the cooking process. Absent disclosure of an ***intragranular phase***, the cited reference does not set forth each and every element of the instantly claimed subject matter and cannot anticipate the pending claims. Applicants respectfully request withdrawal of the rejections and allowance of the pending claims.

#### ***Claim Rejections – 35 U.S.C. § 103***

Claims 1-3, 11-22, 25-32, 34, and 53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Jasprova*. Claims 1-3, 11-34, and 53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Jasprova* in view of Flash-Ner-Barak, et al., WO 02/00204 (hereinafter *Flash-Ner-Barak*). Alternatively, claims 1-3, 11-34, and 53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Jasprova* and *Flash-Ner-Barak* further in view of Katdare, et al., WO 95/29679 (hereinafter *Katdare*). Claim 34 has been canceled. Claims 2-3, 11-13, and 25-33 depend from independent claim 1 and claims 15-24 depend from independent claim 14. Thus, claims 2-3 and 11-33 stand or fall on the application of *Jasprova* and *Flash-Ner-Barak*, alternatively, *Jasprova*, *Flash-Ner-Barak*, and *Katdare*, to independent claims 1 and 14. Applicants respectfully submit the pending claims are patentable in view of the cited references as one of ordinary skill in the art would not seek to modify the disclosure of primary reference to arrive at the instantly claimed subject matter as the reference teaches away from such modifications. MPEP § 2141.02(VI)

states, “A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984)” (emphasis theirs). The Office Action asserts

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to prepare a bisphosphonic acid derivative and a carbohydrate alcohol by a wet granulation process. The person of ordinary skill in the art would have been motivated to make these modifications and reasonably would have expected success because Jasporova discloses that wet or granulation are suitable methods by which formulations can be prepared.

See Office Action at 7. Applicants respectfully disagree with the Office Action’s assertions. Particularly, Applicants note that the *Jasporova* disclosure describes a prior art process of manufacture based on wet granulation. *Jasporova* goes on to disclose the drawbacks associated with the wet granulation process of the prior art:

On the other hand, wet granulation wherein the product is moistened and heated, forms unfavorable conditions for more sensitive organic substances. See *Jasporoava* at 2.

The described process describes the rather lengthy and uneconomical manufacturing process involving granulation. See *Jasporova* at 3.

As is documented below in the Examples, the combination of diluents according to the invention with exclusion of lactose makes it possible to obtain acceptable properties of the tablets in an economic compressing process, regardless of sensitive substances, which is free of any granulation or pre-granulation of the components. That brings about a new sight onto the bisphosphonic acids pharmacy as a whole. See *Jasporova* at 9.

The Office Action statements suggest that *Jasporova*’s description of prior art processes employing wet granulation would be viewed by the ordinarily skilled artisan as an endorsement of the process of wet granulation and its suitability for use in the invention of *Jasporova*. Such

statements completely ignore *Jasporova*'s disclosure of the drawbacks associated with wet granulation and moreover that the inventive subject matter of *Jasporova* is designed to overcome these drawbacks. Applicants contend the ordinarily skilled artisan when given the benefit of the disclosure of *Jasporova* would find the reference teaches away from the granulation process and resultant products. As *Jasporova* teaches away from a granulation process, the ordinarily skilled artisan would not seek to make such products having an *intragranular phase* as instantly claimed and the reference cannot be said to obviate the pending claims. Furthermore, the secondary references do not impact the disclosure of the *Jasporova* reference which teaches away from a granulation process and consequently the presence of the instantly claimed *intragranular phase*. In consideration of the foregoing, Applicants respectfully submit the pending claims are patentable over the cited references an in condition for allowance.

**CONCLUSION**

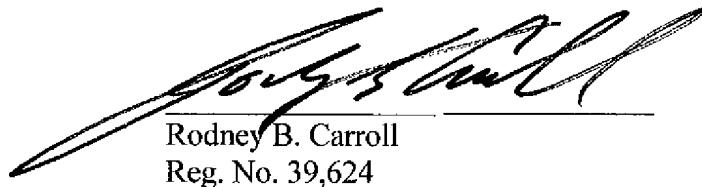
Consideration of the foregoing amendments and remarks, reconsideration of the application, and withdrawal of the rejections are respectfully requested by Applicants. No new matter is introduced by way of the amendment. It is believed that each ground of rejection raised in the Office Action dated January 12, 2010 has been fully addressed. If any fee is due as a result of the filing of this paper, please appropriately charge such fee to Deposit Account Number 50-1515 of Conley Rose, P.C., Texas. If a petition for extension of time is necessary in order for this paper to be deemed timely filed, please consider this a petition therefore.

If a telephone conference would facilitate the resolution of any issue or expedite the prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number given below.

Respectfully submitted,  
CONLEY ROSE, P.C.

Date: \_\_\_\_\_

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